NOV 18 2011

BMK®
Global Medical Company

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92(c).

Date: May 17, 2011

1. Company and Correspondent making the submission:

	Company
Name	BM KOREA Co., Ltd.
Address	325-26, Dangjeong-dong, Gunpo-si, Gyeonggi-do, Republic of Korea 435-832
Phone	+82 31-451-9294
Fax	+82 31-451-9248
Contact	Ju Yun / R&D Assistant Manager

2. Device:
   Proprietary Name – GUARDIAN Inflatable Bone Expander System
   Common Name – Inflatable Bone Tamp
   Classification Name – Arthroscope
   Cement, Bone Vertebroplasty

3. Predicate Device:
   Kyphon Inflatable Bone Tamp, K981251
   KyphX Xpander Inflatable Bone Tamps, K041454

4. Product Code & Regulation Number:
   HRX, 21C.F.R. 880.1100
   NDN, 21C.F.R. 888.3027

5. Description:
   The GUARDIAN, Inflatable Bone Expander System (IBES), is designed to reduce spinal compression fracture and restore sagittal alignment. By creating a space in the vertebral body to facilitate the insertion of bone cement and using cement dispensing plunger, the major benefits of GUARDIAN are the significant reduction in back pain and increase patient's functional abilities, allow a return to the previous level of activity.

The GUARDIAN, Inflatable Bone Expander System components are Inflatable Bone Tamp (balloon catheter, inflation syringe) and accessories kit. And balloon catheter' main components are the shaft, hub and the inflatable balloon located at the distal tip and inflatable balloon is covered maximum 0.03g of silicone fluid to enhance lubricity when the balloon catheter is inserted in the cannula. Radiopaque markers located at the distal and proximal end of deflated working surface allow fluoroscopic visualization of the deflated balloon catheter during positioning.

Accessories kit consists of GUARDIAN Bone Access Needle (starting needle cannula, starting needle trocar), GUARDIAN Osteo Introducer System (guide wire, cannula, trocar-R, trocar-S, drill), GUARDIAN Bone Filler Device (cement bar, cement infusion) and guide impactor.

6. Indication for use:

The GUARDIAN Inflatable Bone Expander System is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebralaugmentation, such as kyphoplasty.

7. Testing:

The GUARDIAN Inflatable Bone Expander System met the specifications and performance characteristics and are substantially equivalent to the predicate devices. The testing included functional, such as balloon compliance, deflation time, insertion/withdraw force and fatigue testing as well as mechanical testing, such as tensile strength.

8. Substantial Equivalence:

The GUARDIAN Inflatable Bone Expander System has the equivalent device characteristics as the predicate device, the Kyphon and KyphX Xpander Inflatable Bone Tamps; intended use, material, design and use concept are similar.

Based on the comparison of intended use and technical features, the GUARDIAN Inflatable Bone Expander System is substantially equivalent to the predicate devices.

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification BM KOREA Co., Ltd. concludes that the GUARDIAN Inflatable Bone Expander System is safe and effective and substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 18 2011

BM KOREA Co., Ltd.
% Arkin Consulting Group, L.L.C.
Mr. Ronald Arkin
1733 Canton Lane
Marietta, Georgia 30062

Re: K111593
Trade Name: GUARDIAN® Inflatable Bone Expander System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: October 13, 2011
Received: October 24, 2011

Dear Mr. Arkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

BMK®
Global Medical Company

Indications for Use

510(k) Number (if known) K111593

Device Name: GUARDIAN ® Inflatable Bone Expander System

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111593